

COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, VA 22313-1450



IAP10 Rec'd PCT/PTO 30 NOV 2005

Docket No.: 478.1072  
Date: November 28, 2005

In re application of: John N. STANIFORTH, et al.  
Serial No.: 10/552,231  
Filed: October 6, 2005  
For: **PHARMACEUTICAL COMPOSITIONS COMPRISING APOMORPHINE FOR PULMONARY INHALATION**

Sir:

Transmitted herewith is an **Information Disclosure Statement** in the above-identified application.

- ☐ Small entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a verified statement previously submitted.
- ☐ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.
- ☐ No fee for additional claims is required.
- ☒ Also transmitted herewith are:
- ☐ Petition for extension under 37 C.F.R. 1.136 (in duplicate)
- ☒ Other: Form PTO-1449 (7 pages);  
Complete set of references cited;  
Appendix A, includes International Search Report issued in International Application No. PCT/GB2004/001627; and  
Return Postcard.
- ☐ Check(s) in the amount of \$ .00 is/are attached to cover:
- ☐ Filing fee for additional claims under 37 C.F.R. 1.16
- ☐ Petition fee for extension under 37 C.F.R. 1.136
- ☐ Other:
- ☒ The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.
- ☒ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
- ☒ Any patent application processing fees under 37 C.F.R. 1.17.
- ☒ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

Cary S. Kappel, Reg. No. 36,561  
DAVIDSON, DAVIDSON & KAPPEL, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
Tel: (212) 736-1940  
Fax: (212) 736-2427

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Examiner: To be assigned

Art Unit: To be assigned

Re: Application of:

John N. STANIFORTH, et al.

Serial No.:

10/552,231

Filed:

October 6, 2005

For:

**PHARMACEUTICAL  
COMPOSITIONS COMPRISING  
APOMORPHINE FOR  
PULMONARY INHALATION****INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

November 28, 2005

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (7 sheets) for consideration by the Examiner in connection with the above-identified patent application.

In accordance with 37 C.F.R. § 1.98(a)(2), copies of non-patent publications and foreign patents are enclosed. If it is determined that any of these references are not enclosed, the Examiner is requested to contact the undersigned so that a missing copy can be provided.

Pursuant to the waiver of the requirement under 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. patents and applications are not enclosed.

The Examiner's attention is directed to references "GH", "GI" and "GL" on sheet 7 of the enclosed Form PTO-1449. These references were cited in the International

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.J./

Search Report issued in International Application No. PCT/GB2004/001627, a copy of the Search Report is enclosed as Appendix A.

Applicants also respectfully advise the Examiner of the following co-pending U.S. patent applications which are commonly assigned to the owners of the instant application:

U.S. Patent Application Serial No. 10/413,022, entitled "Composition, Device, and Method for Treating Sexual Dysfunction Via Inhalation," filed April 14, 2003; and

U.S. Patent Application Serial No. 10/621,964, entitled "Composition, Device and Method for Treating Sexual Dysfunction Via Inhalation," filed July 17, 2003.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 (7 sheets) be considered and made of record.

This Information Disclosure Statement is filed under 37 C.F.R. §1.97 (b), before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due. In the event any additional fee is due or any overpayment made in connection with the filing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge said deficiency or credit overpayment to our Deposit Account No. 50-0552.

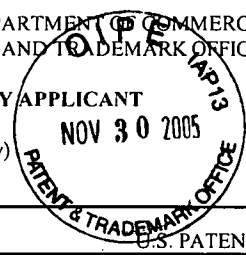
Respectfully submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Cary S. Kappel  
Reg. No. 36,561

DAVIDSON, DAVIDSON & KAPPEL, LLC  
485 Seventh Avenue, 14th Floor  
New York, New York 10018  
(212) 736-1940

--FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 478.1072		SERIAL NO.: 10/552,231	
<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (Use several sheets if necessary)				APPLICANT(S): John STANIFORTH et al.			
				FILING DATE: October 6, 2005		GROUP: To be assigned	



U.S. PATENT DOCUMENTS													
*EXAMINE R INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4	5	2	1	4	2	1	06/04/85	Foreman	514	267	09/26/83
	AB	4	6	8	7	7	7	3	08/18/87	Neumeyer, et al.	514	280	05/31/85
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	AE	5	7	5	6	4	8	3	05/26/98	Merkus	514	58	
	AF	5	7	7	0	6	0	6	06/23/98	El-Rashidy, et al.	514	284	10/20/95
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/S.J./	AH	9	4	2	2	4	4	5	10/13/94	WO (A2)	A61K	31/48			
	AI														
	AJ														
	AK														

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
/S.J./	AL	Padma-Nathan, "Oral Drug Therapy for Female Sexual Dysfunction", Intl J of Impotence Research, Vol 12 Supp 3 (2000) pp S56 -S57
/S.J./	AM	Alexander-Williams, et al., "Novel routes of opioid administration," Brit. J. Anaesth., 1998; 81:3-7
/S.J./	AN	van Laar, et al., "Future delivery systems for apomorphine in patients with Parkinson's disease," Parkinson's Disease: Advances in Neurology, Lippincott Williams & Wilkins, Philadelphia, 1999; 80: 535-544.
/S.J./	AO	Goldstein, et al., "Vasculogenic female sexual dysfunction: vaginal engorgement and clitoral erectile insufficiency syndromes," Int J Impotence Res, 1998; 10(Suppl. 2) S84-S90.
/S.J./	AP	Chustecka, "New treatments for erectile dysfunction", Scrip Reports, PJB Publications Limited, (1998).
/S.J./	AQ	Gower et al., "Antagonism of Drug-induced Yawning and Penile Erections in Rats", European J of Pharmac, Vol 122 (1986) pp 239-244

EXAMINER      /Samira Jean-louis/	DATE CONSIDERED      01/30/2009
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	BA	5	9	8	5	8	8	9	11/16/99	El-Rashidy, et al.	514	284	06/22/98											
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	BG	6	2	9	1	4	7	1	09/18/01	Kling, et al.	514	284	12/17/98											
<b>FOREIGN PATENT DOCUMENTS</b>																								
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/S.J./	BH	9	9	0	9	8	2	8	03/04/99	WO (A1)	A01N	43/42												
	BI																							
	BJ																							
	BK																							
	BL																							
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>																								
/S.J./	BM	Uprima: Scientific Discussion re: Apomorphine in treatment of erectile dysfunction, Abbott Laboratories Ltd. (2001).																						
/S.J./	BN	Summary of Product Characteristics of Apomorphine 2mg and 3 mg sublingual tablets, Abbott Laboratories Ltd. (2001).																						
/S.J./	BO	Heaton et al., "The Characterization of a Bio-Assay of Erectile Function in a Rat Model", J of Urology, Vol 145 (1991) pp 1099-1102																						
/S.J./	BP	Heaton et al., "A Therapeutic Taxonomy of Treatments for Erectile Dysfunction: An Evolutionary Imperative", Intl J of Impotence Research, Vol 9 (1997) pp 115-121																						
/S.J./	BQ	Segraves et al., "Effects of Psychotropic Drugs on Human Erection and Ejaculation", Arch Gen Psychiatry, Vol 46 (1989)																						
EXAMINER										/Samira Jean-louis/					DATE CONSIDERED					01/30/2009				
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/S.J./	CJ	9	9	6	6	9	0	9	12/29/99	WO (A2)	A61K	31/00					
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)																	
/S.J./	CN	Laduron et al., "Domperidone, a Specific in Vitro Dopamine Antagonist, Devoid of In Vivo Central Dopaminergic Activity", Biochem Pharmac., Vol 28 (1979) pp 2161-2165															
/S.J./	CO	Bladessarini et al., "Preclinical Studies of the Pharmacology of Aporphines", Basic Pharmac., Vol 1 (1981)															
/S.J./	CP	Lal et al., "Effect of Domperidone on Apomorphine-Induced Growth Hormone Secretion in Normal Men", J or Neurotransmission, Vol 54 (1982) pp 75-84															
/S.J./	CQ	Heaton, "Neural and Pharmacological Determinants of Erection", Intl j of Impotence Research, Vol 10 Supp 2 (1998) pp S34-S39															
/S.J./	CR	Gancher et al., "Peripheral Pharmacokinetics of Apomorphine in Humans", Annals of Neurology, Vol 26 (1989)															
/S.J./	CS	Heaton et al., "Recovery of Erectile Function by the Oral Administration of Apomorphine", Urology, Vol 45 No 2 (1995)															
/S.J./	CT	Sachs et al., "Effects of Copulation on Apomorphine-Induced Erection in Rats", Pharmacol Biochem & Behavior, Vol 48 No 2 (1994) pp 423-428															
/S.J./	CU	"Oral Medication for Impotence", TLC Pharmacy Men's Newsletter, Issue 2; (downloaded from the internet at <a href="http://tlcpharmacy.com/mends_newsletter_2.html">http://tlcpharmacy.com/mends_newsletter_2.html</a> on Nov. 15, 1998)															
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	DA	5	7	7	0	6	0	6	06/23/98	El-Rashidy	514	284		
	DB	4	0	8	0	4	5	6	03/21/78	Seidelmann, et al.	424	258		
	DC	6	4	0	3	6	0	5	06/11/02	Heaton, et al.	514	284		
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/S.J./	DH	0	0	7	6	5	0	9	12/21/00	WO(A1)	A61K	31/44		
/S.J./	DI	0	1	7	4	3	5	8	10/11/01	WO(A1)	A61K	31/4375		
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/S.J./	DK	0	1	8	2	9	0	6	11/08/01	WO(A1)	A61K	9/72		
	DL													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
/S.J./	DM	Moyer, Female Sexual Dysfunction, Urch Publishing (August 1998)												
/S.J./	DN	Lal, et al., "Apomorphine in the Evaluation of Dopaminergic Function in Man," Prog. Neuro-Psychopharmacol. & Biol. Psychiat. vol 12, pp. 117-164 (1988)												
/S.J./	DO	Harvard Scientific (Harvard Scientific Corp., "Harvard Scientific Acquires Rights to Oral Treatment for Both Male and Female Sexual Dysfunction, pp. 1-3, (Jun. 12, 1998)												
/S.J./	DP	New Perspectives in Management of Female Sexual Dysfunction: Agenda for Oct. 23-25, 1998 conference in Maine												
/S.J./	DQ	Essink, et al., "Selective and Quantitative Isolation and Determination of Apomorphine in Human Plasma", J of Chromatography, Vol 570 (1991) pp 419-424												
/S.J./	DR	Gancher et al., "Absorption of Apomorphine by Various Routes in Parkinsonism", Movement Disorders, Vol 6 No 3 (1991) pp 212-216												
/S.J./	DS	Lal et al., "Effect of Bromocriptine in Patients with Apomorphine-Responsive Erectile Impotence: An Open Study", J Psychiatr Neurosci, Vol 16 No 5 (1991)												
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		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION				
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/S.J./	EB	0	2	2	4	2	0	2	03/28/02	WO(A1)	A61K	31/44		
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/S.J./	EH	1	2	2	4	9	3	3	07/24/02	EP	A61K	31/505		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
/S.J./	EI	Fourcroy, "Issues and Priorities in the Development of Drug Treatments for Female Sexual Dysfunction", International J. Of Impotence Research, 10 Supp 2 (1998)												
/S.J./	EJ	Fernandez-Guasti et al., "Separation of Dopaminergic and Serotonergic Inhibitory Mechanisms in the mediation of Estrogen-Induced Lordosis Behavior in the Rat", Pharm. Biochem. & Behavior, Vol 27 pp 93-98												
/S.J./	EK	Heaton et al., "Effects of Castration and Exogenous Testosterone Supplementation in an Animal Model of Penile Erection", J of Urology, Vol 151 (1994) pp 797-800												
/S.J./	EL	Goodman & Gilman, Pharmacological Basis of Therapeutics, 9 <sup>th</sup> Ed. pp 1-9												
/S.J./	EM	Pehk et al., "Apomorphine and Haloperidol, but not Domperidone, Affect Penile Reflexes in Rats", Pharm Biochem & Behavior, Vol 31 (1998) pp 201-208												
/S.J./	EN	Danjou et al., "Assessment of Erectogenic Properties of Apomorphine and Yohimbine in Man", Br J clin Pharmac, Vol 26 (1988) 733-739												
/S.J./	EO	Tagliamonte et al., "Possible Stimulatory Role of Brain Dopamine in the Copulatory Behavior of Male Rats", Pharmac Biochem and Behavior, Vol 2 (1974) pp 257-260												
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	FK	20	02	00	86	8	7	6	07/04/02	Ruff et al.	514	295	10/10/01						
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	FO	20	02	00	6	9	3	3	01/17/02	Gupta et al.	514	295	03/14/01						
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	FQ	20	02	01	15	6	8	3	08/22/02	Ruff et al.	514	295	11/14/01						
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													YES	NO					
	FR																		
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--FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 478.1072		SERIAL NO.: 10/552,231																		
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)				APPLICANT(S): John STANIFORTH et al.																				
				FILING DATE: October 6, 2005		GROUP: To be assigned																		
U.S. PATENT DOCUMENTS																								
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE											
	GA	20	04	02	04	4	3	9	10/14/04	STANIFORTH, et al.	514	295												
	GB	20	04	02	04	4	4	0	10/14/04	STANIFORTH, et al.	514	295												
	GC																							
	GD																							
	GE																							
	GF																							
	GG																							
FOREIGN PATENT DOCUMENTS																								
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION											
													YES	NO										
/S.J./	GH	01	0	7	4	3	5	8	10/11/01	WO														
/S.J./	GI	03	0	2	6	6	3	1	04/03/03	WO														
/S.J./	GJ	00	0	2	7	3	6	3	05/18/00	WO														
	GK																							
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)																								
/S.J./	GL	"Inhaled Apomorphine Promising for Erectile Dysfunction Treatment," Pharmaceutical Journal; 09 August 03; United Kingdom; Vol. 271, no. 7261, p. 170																						
	GM																							
	GN																							
	GO																							
	GP																							
	GQ																							
EXAMINER										/Samira Jean-louis/					DATE CONSIDERED					01/30/2009				
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